REMARKS

I. Status of the Claims

Claims 1-29, and 31-34 are pending. Claim 30 is cancelled herein. Claims 1-25, 28, 29, 31, and 32 have been amended. Support for the amended claims can be found in original claims 1 through 32. Claims 33 and 34 have been added herein. Support for those claims can be found, for example, at page 96, lines 4-11 of the specification. Accordingly, the claims presented herein all have written description in the specification under 35 U.S.C. § 112, first paragraph.

II. Rejections Under 35 U.S.C. § 101

Claim 30 was rejected under 35 U.S.C. § 101 because the claimed recitation of a use was deemed to be an improper definition of a process. Office Action at 2. Claim 30 has been cancelled herein, thus rendering this rejection moot.

III. Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-32 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In particular, the Office asserted that "[c]laim 1 and dependent claims recite many limitations in parentheses which are not clear if they are part of the claim. Office Action at 3. Applicants have removed the parentheses from all of the pending claims, thus rendering this basis for rejection moot.

The Office also rejected claim 30 as being indefinite. As noted above, claim 30 has been cancelled herein, thus rendering this rejection moot.

The Office rejected claims 28-31 as lacking antecedent basis and being indefinite because those claims recite "prodrug form thereof" whereas claim 1, from which claims 28-31 depend, does not, and the specification does not define what constitutes a "prodrug form." Office Action at 3. Claims 28, 29, and 31 have been amended to delete reference to a prodrug form, thus rendering this rejection moot.

Claim 31 also has been rejected as indefinite. Office Action at 4. The Office asserts that "the limitation of 'anti-proliferative effect' ... is not clear what diseases or organs are intended. The specification does not define what constitutes an 'anti-proliferative effect.'" *Id.* Applicants respectfully disagree.

The specification need not define an anti-proliferative effect. "[A] claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible. M.P.E.P. § 2173.02 *citing Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004) (holding that the disputed claim term "surrender value protected investment credits" which was not defined or used in the specification was discernible and hence not indefinite because "the components of the term have well recognized meanings, which allow the reader to infer the meaning of the entire phrase with reasonable confidence").

Here, however, the specification makes clear the nature of an anti-proliferative effect and that would have been understood by one of ordinary skill in the art. For example, the first sentence of the application states: "The invention concerns certain novel quinazoline derivatives, or pharmaceutically-acceptable salts thereof, which

possess **anti-tumour activity** and are accordingly useful in methods of treatment of the human or animal body." Page 1, lines 2-4 (emphasis added). Page 5, lines 1-3 state (emphasis added): "We have now surprisingly found that certain pyrrolidinyloxyquinazoline derivatives possess **potent anti-tumour activity** and in general have good physical properties, for example good solubility."

Furthermore, the specification explains:

> Without wishing to imply that the compounds disclosed in the present invention possess pharmacological activity only by virtue of an effect on a single biological process, it is believed that **the compounds provide an anti-tumour effect by way of inhibition of one or more of the erbB family of receptor tyrosine kinases that are involved in the signal transduction steps which lead to the proliferation of tumour cells**. In particular, it is believed that the compounds of the present invention provide **an anti-tumour effect by way of inhibition of EGFR and/or erbB2 receptor tyrosine kinases**.
>
> Generally the compounds of the present invention possess **potent inhibitory activity against the erbB receptor tyrosine kinase family, for example by inhibition of EGFR and/or erbB2 and/or erbB4 receptor tyrosine kinases**, whilst possessing less potent inhibitory activity against other kinases. Furthermore, certain compounds of the present invention possess substantially better potency against the EGFR over that of the erbB2 tyrosine kinase. The invention also includes compounds that are active against all or a combination of EGFR, erbB2 and erbB4 receptor tyrosine kinases, thus potentially providing treatments for conditions mediated by one or more of these receptor tyrosine kinases.

Page 5, lines 4-18.

The specification also sets forth 4 different biological assays that "may be used to measure the effects of the compounds of the present invention as **inhibitors of the erb-tyrosine kinases kinases, as inhibitors in-vitro of the proliferation of KB cells ... and as inhibitors in vivo on the growth in nude mice of xenografts of LoVo**

tumour cells ...." Page 84, lines 23-26. Accordingly, the specification does provide representative enzymes.S

Finally, the specification also clarifies diseases:

> Accordingly, **the compounds of the present invention are expected to be useful in the treatment of diseases or medical conditions mediated alone or in part by erbB receptor tyrosine kinases** (especially EGF receptor tyrosine kinase), i.e. the compounds may be used to produce an erbB receptor tyrosine kinase inhibitory effect in a warmblooded animal in need of such treatment. Thus **the compounds of the present invention provide a method for the treatment of malignant cells characterised by inhibition of one or more of the erbB family of receptor tyrosine kinases**....Accordingly the compounds of the present invention are expected to be useful in the **treatment of psoriasis, benign prostatic hyperplasia (BPH), atherosclerosis and restenosis and/or cancer** by providing an anti-proliferative effect, particularly in the treatment of erbB receptor tyrosine kinase sensitive cancers. **Such benign or malignant tumours may affect any tissue and include non-solid tumours such as leukemia, multiple myeloma or lymphoma, and also solid tumours, for example bile duct, bone, bladder, brain/CNS, breast, colorectal, endometrial gastric, head and neck, hepatic, lung, neuronal, oesophageal, ovarian, pancreatic, prostate, renal, skin, testicular, thyroid, uterine and vulval cancers.**

Page 93, lines 7-27; *see also* page 92, ll. 28-31.

Accordingly, the limitation in claim 31 of an anti-proliferative effect is definite. Applicants therefore respectfully request withdrawal of this rejection.

Claim 32 has been rejected as being indefinite because of its recitation of "removed by conventional means." Office Action at 4. Claim 32 has been amended to delete "by conventional means." Accordingly, this rejection has been rendered moot.

IV. Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 28-31 have been rejected under 35 U.S.C. § 112, first paragraph, because "the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making '*prodrug*' of the claimed compounds." Office Action at 4. Claims 28, 29, and 31 have been amended to delete reference to prodrugs, thus rendering this rejection moot.

V. Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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